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|---------------|-------------|-----------------------|---------------------|
| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
| 06/7910, 002  | 12/16/85    | HAGEMAN               | PTO/92-120001       |

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| EXAMINER     |              |
| MAUREY, E.   |              |
| ART UNIT     | PAPER NUMBER |
| L27          | 6            |
| DATE MAILED: |              |
| 03/02/87     |              |

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on \_\_\_\_\_  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1.  Notice of References Cited by Examiner, PTO-892. 2.  Notice re Patent Drawing, PTO-948.  
3.  Notice of Art Cited by Applicant, PTO-1449 4.  Notice of informal Patent Application, Form PTO-152  
5.  Information on How to Effect Drawing Changes, PTO-1474 6.

**Part II SUMMARY OF ACTION**

1.  Claims 1-32 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4.  Claims 1-32 are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8.  Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. These drawings are  acceptable;  not acceptable (see explanation).

10.  The  proposed drawing correction and/or the  proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner,  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved,  disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12.  Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received

been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in

Claims 1-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 and 46-48 of copending application serial no. 724311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are encompassed by the claims of 724311.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16 and 17 are rejected under 35 U.S.C. 101 because the claims are broadly drawn to the cells of a liver and as such are drawn to a natural product. Since no new utility or property is obtained through the hand of man, the claimed product reads on that found in nature Diamond v. Chakrabarty 206 USPQ 193.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure .

The invention appears to employ novel plasmids. It is not clear if the written text is sufficiently descriptive and if the disclosed processes sufficiently repeatable to avoid the need of a deposit for enablement purposes. A deposit was made in this application as filed. However, it is not clear if the deposit meets all of the criteria set forth in MPEP 608.01(p)C. Applicants may provide assurance of compliance with the requirements of §112 in the form of a declaration avering that (a) during the pendency of this applica-

Art Unit 127

tion, access to the deposit will be afforded to the Commissioner upon request,

(b) that all restrictions upon availability to the public will be irrevocably removed upon granting of the patent,

(c) that the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, and

(d) that the deposit will be replaced if it should ever become inviable.

Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 2,3, 6, 7, 11-15, 19-23, 27, 28, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3, 6, 7, 11, 12, 14, 15, 19, 20, 22, 23, 27, 28, 31 and 32 are indefinite in the recitation of "derived from" as it is not clear if a chemical modification or mere isolation is intended. Claims 13, 14, 15, 21, 22 and 23 are indefinite in the recitation of

Art Unit 127

"includes" or "including" as it is not clear if open or closed language is intended. Claims 13, 14, 15, 21, 22 and 23 are indefinite and confusing in the recitation of "RNA splice sites". As this term has alternate art recognized meanings (including for example the sequences immediately surrounding intron/exon boundaries within mammalian structural genes) and has not been explicitly defined in the specification, the sequences and functions encompassed by this language are not clearly set forth. Claims 11, 12, 19, 20, 27 and 28 are indefinite in the recitation of "at least a portion of." A single nucleotide can be a "portion".

Claims 1-32 are free of the prior art.

Any inquiry concerning this communication should be directed to Karen Maurey at telephone number 703-557-0296.

KM

Maurey:bjk

2/20/87



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SUPERVISORY PATENT EXAMINEE  
ART UNIT 127